

REMARKS

Claims 1, 14-20, 22-30, 36-38, 41, 117-122, and 124-136 are pending in the application. Claims 2-13, 21, 31-35, 39-40, 42-116, and 123 have been cancelled in prior Replies without prejudice to, or disclaimer of, the subject matter thereof. Applicants reserve the right to file continuation applications directed to the subject matter of any claim cancelled for any reason.

Rejection of Claims 1, 14-15, 18-20, 22-30, 36-38, 41, 117-120, 122, and 124-136 under 35 U.S.C. § 103(a) over Riley in view of Wakat

Claims 1, 14-15, 18-20, 22-30, 36-38, 41, 117-120, 122, and 124-136 are rejected under 35 U.S.C. § 103(a). Paper No. 15 at pages 2-3. Specifically, the Examiner asserts that these claims are “unpatentable over Riley (US 5,976,568) in view of Wakat (US 6,054,128).” *Id.* at page 2. Applicants respectfully traverse.

To maintain a proper rejection under 35 U.S.C. § 103, the USPTO must meet four conditions to establish a *prima facie* case of obviousness. First, the USPTO must show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, the USPTO must show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an applicant’s disclosure. Third, the prior art must teach or suggest all the claim limitations. *In re Vaack*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Fourth, if an obviousness rejection is based on some combination of prior art references, the USPTO must show the suggestion, teaching, or motivation to combine the prior art references. *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). The showing of the suggestion, teaching, or motivation to combine must be “clear and particular.” *Id.* Broad conclusory statements about the teaching of multiple references, standing alone, are not “evidence.” *Id.*

Independent claim 1 defines a composition for supplementing nutritional deficiencies in a patient or person in need thereof, comprising about 45 mg to about 55 mg vitamin C, about 31.5 IU to about 38.5 IU vitamin E, about 180 µg to about 220 µg chromium, about 63 µg to about 77 µg selenium, about 18 mg to about 22 mg zinc, B-complex other than folic

acid, and at least 800 µg folic acid, wherein the composition is administerable to a patient or person.

Independent claim 37 claims a composition for supplementing nutritional deficiencies in a patient or person in need thereof, comprising about 45 mg to about 55 mg vitamin C, about 31.5 IU to about 38.5 IU vitamin E, about 2.25 mg to about 2.75 mg folic acid, about 270 µg to about 330 µg biotin, about 9 mg to about 11 mg pantothenic acid, about 180 µg to about 220 µg chromium, about 63 µg to about 77 µg selenium, about 18 mg to about 22 mg zinc, about 18 mg to about 22 mg niacin, about 13.5 mg to about 16.5 mg pyridoxine, about 1.8 mg to about 2.25 mg riboflavin, about 10.8 µg to about 13.2 µg cyanocobalamin, and about 2.7 mg to about 3.3 mg thiamine, wherein the composition is administerable to a patient or person.

Independent claim 117 claims a composition for supplementing nutritional deficiencies in a patient or person in need thereof, comprising about 45 mg to about 55 mg vitamin C, about 31.5 IU to about 38.5 IU vitamin E, about 63 µg to about 77 µg selenium, about 18 mg to about 22 mg zinc, B-complex other than folic acid, and at least 800 µg folic acid, wherein the composition is administerable to a patient or person.

Independent claim 134 claims a composition for supplementing nutritional deficiencies in a patient or person in need thereof, comprising about 45 mg to about 55 mg vitamin C, about 31.5 IU to about 38.5 IU vitamin E, about 2.25 mg to about 2.75 mg folic acid, about 270 µg to about 330 µg biotin, about 9 mg to about 11 mg pantothenic acid, about 63 µg to about 77 µg selenium, about 18 mg to about 22 mg zinc, about 18 mg to about 22 mg niacin, about 13.5 mg to about 16.5 mg pyridoxine, about 1.8 mg to about 2.25 mg riboflavin, about 10.8 µg to about 13.2 µg cyanocobalamin, and about 2.7 mg to about 3.3 mg thiamine, wherein the composition is administerable to a patient or person.

Riley fails to teach or suggest each and every element of independent claims 1, 37, 117, and 134. Specifically, the Examiner admits, "Riley does not teach expressly that the amount of folic acid is at least about 800 mcg, or the particular amounts range of each and every ingredients." Paper No. 15 at page 2. The attention of the Examiner is respectfully directed to the fact that the compositions of independent claims 1, 37, 117, and 134 comprise at least 800 µg folic acid. As such, Riley cannot support the present rejections.

Further, Applicants assert that the Examiner has failed to show any suggestion, teaching, or motivation derived from the references of record to combine the alleged

teachings of Riley and the alleged teachings of Wakat to produce the compositions defined by any one of independent claim 1, independent claim 37, independent claim 117, and independent claim 134. In addition, the Examiner's broad and conclusory contention that "it would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed ... invention was made, to employ more than 800 mcg of folic acid in an oral dosage form" (Paper No. 15 at page 3) and that "[a] person of ordinary skill in the art would have been motivated to employ more than 800 mcg of folic acid in an oral dosage form because folic acid are [sic] known to be supplemented up to 10 mg" (Paper No. 15 at page 3) have no support.

The Examiner must show that the references of record teach or suggest the claimed invention. "When obviousness is based on a particular prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference." *B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1582 (Fed. Cir. 1996). Indeed, the Examiner has selectively picked, without either the requisite teaching or suggestion thirteen of the thirty-five micronutrients separately listed in claim 1 of Riley, and thirteen of the thirty-three micronutrients separately listed in Table II and III of Riley. The Examiner then selectively picked, without the requisite teaching or suggestion one of the thirteen micronutrients separately listed in, for example, claim 3 of Wakat to combine with Riley. The Examiner puts forth no motivation to combine these selected micronutrients from Riley and Wakat.

The Examiner cannot pick and choose from the primary and secondary references, in hindsight reconstruction, the specific elements of the composition of the present invention to create an obviousness rejection. "One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to depreciate the claimed invention." *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988). Both the suggestion and the reasonable expectation of success for one of ordinary skill in the art to make and use the compositions of Applicants' independent claims is absent from the references of record, as well as the requisite teaching or suggestion of all the elements of the independent claims. Indeed, the Examiner makes no *prima facie* case of obviousness. If the Examiner maintains the present rejections, Applicants respectfully request that the Examiner specifically address the claimed ranges and support the contentions within a reference to be made of record pursuant to M.P.E.P. § 706.02(j).

Accordingly, the claimed compositions would not have been obvious in view of the cited references of record and Applicants respectfully request that the present rejection of claims 1, 14-15, 18-20, 36-38, 41, 117-120, 122 and 124-136 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

Rejection of Claims 16 and 17 under 35 U.S.C. § 103(a) over Riley in view of Wakat and in further view of McLeod

Claims 16 and 17 are rejected under 35 U.S.C. § 103(a). Paper No. 15 at pages 3-4. Specifically, the Examiner asserts that these claims are “unpatentable over Riley (US 5,976,568) in view of Wakat (US 6,054,128) ... and in further view of McLeod (US 5,898,036).” *Id.* at Page 3. Applicants respectively traverse.

Claim 16 and claim 17 comprise each and every limitation of independent claim 1. As established above, Riley alone or in combination with Wakat fails to teach or suggest each and every element of independent claim 1. Specifically, the Examiner admits, “Riley does not teach expressly that the amount of folic acid is at least about 800 mcg, or the particular amounts range of each and every ingredients.” Paper No. 15 at page 2. In addition, the Examiner admits that “Riley and Wakat do not teach expressly the particular chromium salts” within compositions defined by claim 16 and/or by claim 17. Paper No. 15 at page 3.

McLeod fails to remedy the deficiencies of Riley and Wakat as it fails, either singly or in combination, to teach or suggest each and every element of compositions defined by independent claim 1, from which claims 16 and 17 depend. Specifically, for example, McLeod fails to teach or suggest any composition for supplementing nutritional deficiencies in a patient or person in need thereof, comprising about 45 mg to about 55 mg vitamin C, about 31.5 IU to about 38.5 IU vitamin E, about 63 µg to about 77 µg selenium, about 18 mg to about 22 mg zinc, B-complex other than folic acid, and at least 800 µg folic acid, wherein the composition is administerable to a patient or person, let alone any composition defined by any one of independent claim 1, dependent claim 16, and dependent claim 17. As such, McLeod is deficient to support the present rejections of claim 16 and claim 17, either alone or in combination with one or both of Riley and Wakat.

Moreover, the Examiner has failed to show any suggestion, teaching, or motivation derived from the references of record to combine the alleged teachings of McLeod with any

one or both of the alleged teachings of Riley and the alleged teachings of Wakat to produce the compositions defined by either claim 16 or by claim 17. The Examiner has not met the requirement, imposed by the Federal Circuit, that the Examiner make a “clear and particular” showing of the reasons one of ordinary skill in the art would have been motivated to select Riley, Wakat, and McLeod and to combine Riley, Wakat, and McLeod to arrive at compositions defined by either claim 16 or by claim 17. *In re Dembiczak*, 50 U.S.P.Q.2d at 1617. Indeed, the combination by the Examiner of Riley, Wakat, and McLeod without such a showing has led the Examiner to the “hindsight trap” long criticized by the Federal Circuit. *Id.*

Accordingly, the claimed compositions would not have been obvious in view of the cited references of record and Applicants respectfully request that the present rejection of Claims 16 and 17 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

Rejection of Claim 121 under 35 U.S.C. § 103(a) over Riley in view of Wakat and in further view of Anderson

Claim 121 was rejected under 35 U.S.C. § 103(a). Paper No. 15 at page 4. Specifically, the Examiner asserts that claim 121 is “unpatentable over Riley (US 5,976,568) in view of Wakat (US 6,054,128) ... and in further view of Anderson (US 5,278,329).” *Id.* Applicants respectively traverse.

Claim 121 comprises each and every limitation of independent claim 117. As established above, Riley alone or in combination with Wakat fails to teach or suggest each and every element of independent claim 117. Specifically, the Examiner admits, “Riley does not teach expressly that the amount of folic acid is at least about 800 mcg, or the particular amounts range of each and every ingredients.” Paper No. 15 at page 2. In addition, the Examiner admits that “Riley and Wakat do not teach expressly the particular zinc salts” within compositions defined by claim 121. Paper No. 15 at page 4.

Anderson fails to remedy the deficiencies of Riley and Wakat as it fails, either singly or in combination, to teach or suggest each and every element of compositions defined by independent claim 117, from which claim 121 depends. Specifically, for example, Anderson fails to teach or suggest any composition for supplementing nutritional deficiencies in a patient or person in need thereof, comprising about 45 mg to about 55 mg vitamin C, about 31.5 IU to about 38.5 IU vitamin E, about 63 µg to about 77 µg selenium, about 18 mg to

about 22 mg zinc, B-complex other than folic acid, and at least 800 µg folic acid, wherein the composition is administerable to a patient or person, let alone any composition defined by any one of independent claim 117 or dependent claim 121. As such, Anderson is deficient to support the present rejection of claim 121, either alone or in combination with one or both of Riley and Wakat.

Moreover, the Examiner has failed to show any suggestion, teaching, or motivation derived from the references of record to combine the alleged teachings of Anderson with any one or both of the alleged teachings of Riley and the alleged teachings of Wakat to produce the compositions defined by claim 121. Again, it is respectively submitted that the Examiner has not met the requirement, imposed by the Federal Circuit, that the Examiner make a “clear and particular” showing of the reasons one of ordinary skill in the art would have been motivated to select Riley, Wakat, and Anderson and to combine Riley, Wakat, and Anderson to arrive at compositions defined by claim 121. *In re Dembiczak*, 50 U.S.P.Q.2d at 1617. Indeed, the combination by the Examiner of Riley, Wakat, and Anderson without such a showing has led the Examiner to the “hindsight trap” long criticized by the Federal Circuit. *Id.*

Accordingly, the claimed compositions would not have been obvious in view of the cited references of record and Applicants respectfully request that the present rejection of Claim 121 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

Response to the Arguments

The Examiner’s citation throughout Paper No. 15 of *In re Boesch*, 617 F.2d 272 (Fed. Cir. 1980) with respect to the instant application is inapposite. Paper No. 15 at pages 3 and 4-5. The case cited by the Examiner addressed claims wherein “the requirements of the claims and the cited references” allegedly overlapped. *In re Boesch*, 617 F.2d at 276. As outlined above, with respect to at least one limitation of each and every one of independent claim 1, independent claim 37, independent claim 117, and independent claim 134, no such overlap with the references of record exists.

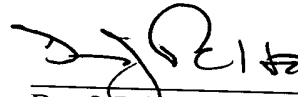
CONCLUSION

Applicants respectfully request that the Examiner consider the present remarks and reconsider and withdraw the present rejections. Should there be any further matters requiring consideration, the Examiner is invited to contact the undersigned counsel.

If there are any fees due in connection with the filing of this Reply, please charge the fees to undersigned's Deposit Account No. 50-1067. If any extensions or fees are not accounted for, the extensions are requested and the fees should be charged to said deposit account.

Respectfully submitted,

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